

Recommendation to FDA/TPSAC Relative to Dissolvable Tobacco Products, with reference to IOM Report on *Scientific Standards for Studies on Modified Risk Tobacco Products*

Introduction and Abstract:

This is a written comment being submitted to the FDA Tobacco Products Science Advisory Committee (TPSAC) the context of their January 19, 2012 meeting relative to dissolvable tobacco products. **The purpose of this comment is to urge TPSAC consideration of these smokeless tobacco products in the context of the broader literature relative to risks posed by smokeless tobacco products.** In this context, **I (JLN) urge that TPSAC recommend FDA classification of dissolvable tobacco products as a relatively low risk alternative to cigarettes. This would allow dissolvable tobacco products to be marketed without imposing a requirement for extraordinary difficult product-specific epidemiological studies.**

Dissolvables in the Context of the IOM Report:

It comes as no surprise that Section 911 of the Family Smoking Prevention and Tobacco Control Act (FSPTCA) makes it impractical, if not physically impossible, for any non-pharmaceutical tobacco product to qualify as “modified risk” or “reduced exposure.” Section 911 reflects the opinion of some tobacco control activists that any new tobacco product will increase teen initiation of tobacco use. It also reflects the desire of major pharmaceutical firms and Altria/Philip Morris to protect their principle nicotine delivery products from competition from less expensive and possibly more satisfying alternatives.

This bias created a situation in which the FDA charge to this IOM committee was problematic with regard to the following issues:

1. FDA has not formally considered the literature definitively showing that **the smokeless tobacco products currently on the American market pose a risk of fatal cancer, heart and lung disease less than 1% the risk posed by cigarettes.**
2. FDA has not formally considered the literature definitively showing that the smokeless tobacco products on the American market since the mid-1980's pose no perceptible risk of oropharyngeal cancer. (This is a risk currently limited to poorly made and highly contaminated smokeless tobacco products widely available in India and selected other countries, but not in the USA.)
3. FDA has not considered the possibility that a tobacco harm reduction program could substantially reduce tobacco-attributable mortality among smokers currently unable or unwilling to quit. Furthermore, the FDA has not considered the possibility that **this public health benefit could be secured with little or no adverse impact on nicotine initiation rates by teens or on quit rates by current smokers.** In this context, “tobacco harm reduction” (THR) is defined as informing smokers of the differences in risk of potentially fatal illness, comparing cigarettes to smoke-free and other alternatives. THR would be integrated into current tobacco control programming as a fallback position for smokers unable or unwilling to quit and those who have tried the pharmaceutical alternatives without success. Both public sector and tobacco company messaging would be guided and controlled by federal agencies and other public health authorities.

While **the FSPTCA prohibits risk-related communications by tobacco companies, it does nothing to restrict risk-related communications by federal or other public health authorities.**

All this, in turn, creates an urgent need for FDA sponsored policy deliberations along the following lines:

1. **Tobacco products** (both pharmaceutical and non-pharmaceutical) **should be divided into classes, based on the nature of the tobacco product**, with each class offering a distinctive risk profile. In this classification, combustible products would consist of a set of high risk classes, with cigarettes likely highest in risk. Smokeless would consist of several classes, of much lower risk. The lowest risk class would likely be the pharmaceutical NRT products and e-cigarettes.
2. **FDA should specify what risk-related statements tobacco companies could make *based on the class of product*.**
3. The provisions of Section 911 of the FSPTCA should then be implemented as follows:
 - a. Cigarette makers and makers of other combustible tobacco products seeking “modified risk” or “reduced exposure” designation would have to fully comply with the study guidelines specified in the IOM report. They would also have to demonstrate that their product modifications would reduce the risk of tobacco-attributable mortality to the level posed by the smokeless products referenced above. Modified risk status designation based on smaller reductions in risk would not be considered by FDA to avoid a repeat of the light/low tar cigarette fiasco.
 - b. **Dissolvables should be recognized as smoke-free products, with their level of risk within this set of classes based on their chemical profile as compared to chewing tobacco, snus, and the pharmaceutical nicotine replacement therapy products.**
 - c. Surveillance of tobacco product sales, tobacco product utilization, and health impacts would be conducted by or on behalf of FDA and CDC, funded by the fees paid by tobacco companies under the FSPTCA. This surveillance would be supplemented by a research agenda intended to refine our estimates of health risks associated with each class of tobacco product.
 - d. All this would be in addition to FDA regulation of quality of manufacture and marketing under the FSPTCA.

Reviews of the scientific **literature supporting the opinions noted above** have already been submitted to FDA by me and multiple other proponents of tobacco harm reduction. Perhaps the most succinct and easily accessed literature reviews along these lines **can be found on the Tobacco page of the American Association of Public Health Physicians website** at www.aaphp.org/tobacco. This page includes links to a 2008 Resolution and White Paper plus 2010 and 2011 literature updates on tobacco harm reduction. It also includes two citizen petitions to FDA with over 300 pages of attached reference materials dealing with e-cigarettes.

Disclosure Statement

Neither the author of this essay (Dr. Joel Nitzkin), nor the American Association of Public Health Physicians (AAPHP) has received any financial support from any pharmaceutical or tobacco firm. This work has been done and continues to be done on a voluntary basis for the sole purpose of reducing the toll of tobacco-attributable illness and death in the USA. I am submitting this document to TPSAC as an individual since time between announcement and deadline precluded formal AAPHP review.

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